

## Remarks

The examiner rejected claim 10 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as their invention. The Examiner argues that claim 10 is indefinite in the recitation less than about 20.

Based on the amendment herein the applicants believe that they have particularly pointed out and distinctly claimed the subject matter that they regard as their invention. Therefore, the applicants request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn and the claims allowed to issue.

The Examiner rejected claims 1-5, 7, 8, 10, 12 and 13 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,607,721 to Ulman in view of U.S. Patent No. 5,785,978 to Porter. The Examiner argues that Ulman teaches that due to the presence of the siloxylated polyether component, the adhesive composition are especially suitable for delivering hydrophilic bioactive agent to a patient's skin. The Examiner further argues that Ulman teaches that the adhesive compositions are prepared by missing the PSA with the siloxylated polyether and that the bioactive agent can be incorporated into the adhesive composition. The Examiner states that Ulman does not explicitly define at what state of mixing that the bioactive agent is added. However, the Examiner argues that there are a limited number of possibilities for the addition order of the components. The Examiner also states that Ulman does not explicitly disclose suitable forms (i.e. solid) of the bioactive agent. The Examiner relies on Porter to demonstrate that it is well known to add powdered active agents to silicone pressure sensitive adhesives.

Ulman discloses blend of a silicone pressure sensitive adhesive and a siloxylated polyether wax. The compositions are prepared by mixing the silicone pressure sensitive adhesive with the siloxylated polyether wax. Ulman does not specifically teach how the drug is incorporated into the blend.

Porter teaches the use of ascorbic acid or sodium ascorbate in dry powder form suspended in a dry matrix. Porter teaches the blending ascorbic acid into a silicone PSA (see Example 2.1). Porter does not teach or suggest the use of silicone polyethers or siloxylated polyether waxes to improve the compatibility of the ascorbic acid with the PSA.

Applicant claims a method of making an adhesive matrix containing an adhesive and a solid powdered hydrophilic excipient. In order to make the matrix the excipient is first blended with a silicone polyether. The silicone polyether claimed herein is not a silicone polyether wax. There is nothing in Ulman that would motivate one skilled in the art to remove the wax group from the silicone polyether with an expectation that it would still have compatibility with a hydrophilic excipient.

Further as seen by the attached affidavit there are unexpected results when the method of the instant invention is used. Micrographs were taken when the excipient was mixed into the PSA/polyether mixture vs. when the excipient was mixed with the polyether first and then with the PSA. For niacinamide, a hydrophilic drug, it can be seen that the particle size was much smaller when using the method of the instant invention. The same was true for lidocaine. Further, as can be seen there is a statistically significant difference in drug release rates for niacinamide. There is nothing in Ulman or Porter that would have suggested these results.

The Examiner has rejected claims 6, 9, and 11 under 35 U.S.C. §103(a) as being unpatentable over Ulman in view of Porter as applied above, and further in view of U.S. Patent No. 6,337,086

to Kanios. The Examiner argues that Ulman teaches that silicone PSAs are known in the art and are typically solvent based adhesives. However, the Examiner states that Ulman does not teach the use of polydiorganosiloxane gums. The Examiner then argues that Kanios teaches PSAs that contain polydiorganosiloxane gums and the use of solvents when using gums. The Examiner concludes that since Ulman does not teach the amount of solvent in the PSA that the ordinary artisan would look to literature for guidance on this parameter and would be motivated to use values known in the art for similar PSA compositions, such as those taught by Kanios.

As demonstrated above, the claimed invention is not obvious over Ulman in view of Porter based on achieving unexpected results when using a specific order of addition. Kanios does not add to that teaching to make claims 6, 9 and 11 obvious.

The Examiner has non-provisionally rejected claims 1-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,607,721 in view of Porter.

Since Applicant's have demonstrated that the claims 1-13 are not obvious over U.S. Patent No. 5,607,721 in view of Porter, Applicant considers this rejection moot.

This reply is being submitted within the period for response to the outstanding office action. Although the applicants believe in good faith that no extensions of time are needed, the applicants hereby petition for any necessary extensions of time. You are authorized to charge deposit account 04-1520 for any fees necessary to maintain the pendency of this application. You are authorized to make any additional copies of this sheet needed to accomplish the purposes provided for herein and to charge any fee for such copies to deposit account 04-1520.

Respectfully Submitted,  
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